

Applicant: Cy A. Stein et al.  
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Filed: January 2, 2001  
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**REMARKS**

Claims 5, 9, and 43 are pending and under examination in the subject application. By this Amendment, applicants have amended claims 5, 9, and 43. Applicants maintain that the amendments to the claims raise no issue of new matter. Support for the amendments to claim 5 may be found in the specification at, *inter alia*, page 3, lines 2-5; page 15, lines 1-3; page 5, lines 20-25; page 5, lines 3 and 28; page 1, lines 21-22; and in originally filed claim 1. Support for the amendments to claim 9 may be found in the specification at, *inter alia*, page 3, lines 2-5; page 15, lines 1-3; page 5, lines 20-25; page 5, lines 3 and 28; page 1, lines 21-22; and in originally filed claim 1. Support for the amendments to claim 43 may be found in the specification at, *inter alia*, page 19, lines 15-18. Accordingly, applicants respectfully request entry of this Amendment. After entry of this Amendment, claims 5, 9, and 43 will be pending and under examination.

Applicants note that a previous Amendment in response to the May 19, 2004 Final Office Action was filed August 19, 2004. As stated in a September 2, 2004 Advisory Action in connection with the above-identified application, that Amendment was not entered.

**Claims Rejected Under 35 U.S.C. §112 (Enablement)**

In the May 19, 2004 Final Office Action, the Examiner stated that claim 43 remains rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for using the pharmaceutical compositions of the instant invention in an *in vitro* method, does not reasonably provide enablement for using the claimed pharmaceutical compositions *in vivo* for therapeutic purposes. The Examiner further stated that the specification does

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not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim, for the reasons of record set forth in the Office Action mailed 6-18-03.

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, but without conceding the correctness of the Examiner's argument, applicants have hereinabove amended claim 43. As amended, claim 43 does not recite a "pharmaceutical composition". Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

**Claims Rejected Under 35 U.S.C. §112 (Written Description)**

The Examiner stated that claim 43 remain rejected, and claim 5 is rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner stated that the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the Official Action mailed 1-05-04. The Examiner also stated that applicants' arguments filed 3-08-04 have been fully considered but they are not persuasive, and that applicants traverse the instant rejection on the grounds that by amending claim 5 to recite "consisting essentially" instead of comprising, and to recite a functional characteristic of the claimed oligonucleotide, the claims are now more clearly defined, and the rejection should be withdrawn. The Examiner further stated that the transitional phrase "consisting essentially of" limits the scope of the claims to the specified matter, and those that do

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not materially affect the basic and novel characteristics of the claimed invention, see MPEP §2111.03. The Examiner also stated that the specification as filed do not define what factors or structural features that may be added to the claimed oligonucleotides, wherein such additions do not materially affect the basic and novel characteristics of the claimed invention.

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, but without conceding the correctness of the Examiner's argument, applicants have hereinabove amended claim 5. As amended, claim 5 recites the characteristic of "10 or more contiguous bases of [specific nucleotide sequences]". Accordingly, applicants maintain that the claimed subject matter is clearly described, and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

#### **Double Patenting**

The Examiner stated that claims 5, 9 and 43 remain provisionally rejected under the judicially created doctrine of double patenting over claims 9, 36-50, 53-54, 58, and 61-62 of copending Application No. 09/832,648 in view of Manoharan et al. Sanghvi et al, Matteucci et al. and Arnold et al. for the reasons of record set forth in the prior Office Action mailed 6-18-03. In addition, the Examiner stated that claims 5, 9, and 43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 37-43, 51-53, 58, and 61-62 of copending Application No. 10/160,344.

In response, applicants respectfully traverse the Examiner's rejection. However, applicants respectfully note that the claims of the co-pending applications referred to by the Examiner have

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not been allowed, and that if the Examiner's remaining rejections are obviated by the amendments and arguments made hereinabove then the pending claims should be allowed in the absence of the allowance of the applications over which the double patenting rejections have been made.

Accordingly, in light of the arguments and amendments made hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the various grounds of rejections, and allow claims 5, 9, and 43.

Applicants wish to make it clear on the present record that the inventive entity of subject matter claimed in claims 9, 36-50, 53-54, 58 and 61-62 of copending application no. 09/832,648 is Cy Stein, and the inventive entity of the subject matter claimed in claims 37-43, 51-53, 58, and 61-62 of copending application 10/160,344 is Cy Stein, Paul Cossum, Robert Rando and Joshua Owjang. This should be apparent from the list of inventors in these respective applications. In all of the relevant applications, inventor Cy Stein has assigned his rights to The Trustees of Columbia University in the City of New York, and inventors Paul Cossum, Robert Rando and Joshua Owjang have assigned their rights to Aronex Pharmaceutical Inc.

#### **Information Disclosure Statement**

Applicants note that a Supplemental Information Disclosure Statement was filed on May 7, 2004 in connection with the above-identified application, shortly before the issuance of the May 19, 2004 Office Action. Accordingly, applicants request that the Examiner forward to them an initialed copy of the PTO-1449 filed as Exhibit A in connection with the May 7, 2004 Supplemental Information Disclosure Statement.

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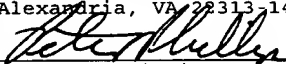
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, apart from the \$55.00 fee for a one month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any such fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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